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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte PHILIP A. CARPINO and ROBERT L. DOW

Appeal 2009-010577
Application 10/823,152
Technology Center 1600

Decided: April 19, 2010

Before ERIC GRIMES, LORA M. GREEN, and STEPHEN WALSH,
Administrative Patent Judges.

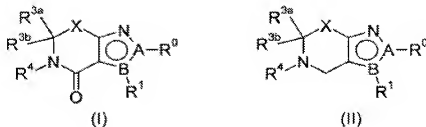
WALSH, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to bicyclic pyrazolyl imidazolyl compounds. The Patent Examiner rejected the claims on the ground of nonstatutory obviousness-type double patenting. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

The invention relates to compounds of Formula (I) or (II), said to act as cannabinoid receptor ligands, particularly as CB1 receptor antagonists:



(Spec. 3:16 – 4:20.)

Claims 1, 4, 8-11, 31, 35, 36, 42, 43, 49, 55, 59 and 64, which are all the pending claims, are on appeal. (App. Br. 5.) Appellants provided a copy of the claims in the Claims Appendix of the Appeal Brief dated Sept. 15, 2008. (App. Br. 19-23.)

The Examiner rejected the claims on the ground of nonstatutory obviousness-type double patenting over claims 1-23 of U.S. Patent No. 7,230,024¹ (“the ‘024 patent”). (Ans. 5-14.)² Claims 4, 8-11, 31, 35, 36, 42, 43, 49, 55, 59 and 64 have not been argued separately and therefore stand or fall with claim 1. 37 C.F.R. § 41.37(c)(1)(vii).

NONSTATUTORY OBVIOUSNESS-TYPE DOUBLE PATENTING

The Issue

The Examiner’s position is: “[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because the

¹ US 7,230,024 B2, issued to Philip A. Carpino and Robert L. Dow, Jun. 12, 2007.

² The Answer omitted claim 11 from the rejection. The omission was corrected in an Office communication mailed Dec. 16, 2008.

structures are very similar and the compounds are isomers and hence *prima facie* obvious.” (Ans. 6.) The Examiner reasons that “[b]oth [Appellants’] compounds and those of the patent have the same pyrazole with the 2 phenyl rings. Thus one of skill in the art would consider that the isomers with the different position of the =O . . . also have the same activity, thus motivating a person skilled in the art to try, with a definite amount of predictability of being successful.” (*Id.* at 13.)

Appellants contend that although the compounds now claimed and the compounds claimed in the ‘024 patent are structural isomers, (1) “one can easily see that access to the carbonyl is hindered in one of the structures but not in the other one,” and (2) “the closeness of the R^{3a} and R^{3b} substituents on one orientation would have more influence on the phenyl group than the other orientation.” (App. Br. 16.) According to Appellants,

[i]t is well known that binding to a receptor can be influenced by the orientation of the groups on the compound; consequently, one would not be able to predict with any certainty that such a compound would work until it was made and tested. Therefore, it would not be obvious that the compounds of the present invention would even bind to the CB-1 receptor let alone act as a CB-1 antagonist/inverse agonist based on the compounds disclosed and claimed in US 7,230,024. (*Id.*)

The Examiner found Appellants’ arguments unpersuasive in view of prior art³ that described the compound SR 141716, which had a 2-phenyl pyrazole structure and cannabinoid receptor binding activity. (Ans. 17-18.) In the Examiner’s evaluation, the SR 141716 evidence suggested that

³ Giancarlo Colombo et al., *Appetite Suppression And Weight Loss After The Cannabinoid Antagonist SR 141716*, 63 LIFE SCIENCES 113-117 (1998).

“making changes on the other end of the pyrazole would not affect the activity.” (*Id.* at 17.)

The issues relevant to this appeal are:

was the Examiner’s evidence sufficient to make a *prima facie* case of obviousness; and

if the Examiner’s evidence established a *prima facie* case of obviousness, did Appellants produce persuasive rebuttal evidence of unobviousness?

Findings of Fact

We adopt the facts found in the Examiner’s Answer.

Principles of Law

When chemical compounds have “very close” structural similarities and similar utilities, without more a *prima facie* case [of obviousness] may be made. See for example *In re Wilder*, 563 F.2d 457 . . . (CCPA 1977) (adjacent homologues and structural isomers); *In re May*, 574 F.2d 1082 . . . (CCPA 1978) (stereoisomers); *In re Hoch*, 428 F.2d 1341 . . . (CCPA 1970) (acid and ethyl ester). When such “close” structural similarity to prior art compounds is shown, in accordance with these precedents the burden of coming forward shifts to the applicant, and evidence affirmatively supporting unobviousness is required.

In re Grabiak, 769 F.2d 729, 731 (Fed. Cir. 1985). “The evidence [affirmatively supporting unobviousness] may take various forms, as relevant in the particular case.” *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1086 (Fed. Cir. 2008). However, “obviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as

there was a reasonable probability of success.” *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007). “Obviousness does not require absolute predictability of success. . . . [A]ll that is required is a reasonable expectation of success.” *In re O’Farrell*, 853 F.2d 894, 903-04 (Fed. Cir. 1988).

Analysis

We agree with the Examiner that the close structural similarity of the compounds now claimed to the cannabinoid receptor binding compounds claimed in the ‘024 patent was sufficient for a prima facie case of obviousness. Appellants argue that “[I]n cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound.” *Takeda Chem. Industries, Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1357 (Fed. Cir. 2007). The facts in *Takeda* are distinguishable. The issue in *Takeda* concerned the obviousness of the choice of lead compound for further modification, not the obviousness of one isomer over another. We are guided by the *Grabiak* analysis, which our reviewing court restated after deciding *Takeda*. See *Sanofi-Synthelabo*, 550 F.3d at 1086 (“Precedent establishes the analytical procedure whereby a close structural similarity between a new chemical compound and prior art compounds is generally deemed to create a prima facie case of obviousness, shifting to the patentee the burden of coming forward with evidence of nonobviousness.”).

We also agree with the Examiner that Appellants’ arguments are not the kind of evidence needed to support a conclusion of nonobviousness.

Evidence, not attorney argument, is needed here. Appellants argue that receptor binding “can be influenced” by substituent orientation, and one could not predict “with any certainty” that an isomer would work until it was made and tested. Assuming there is some possibility of uncertainty about how well an isomer would bind the receptor, “certainty” is not the standard. *See O’Farrell*, 853 F.2d at 903-04. Further, the Examiner produced evidence indicating that the claimed isomers would have been expected to bind the receptor, notwithstanding the change in substituent orientation. (Ans. 18, discussing Colombo’s SR 141716.) That evidence also supports the Examiner’s finding that there would have been a reasonable expectation of success. *See Pfizer*, 480 F.3d at 1364.

CONCLUSIONS

The Examiner’s evidence was sufficient to make a prima facie case of obviousness.

Appellants did not produce persuasive evidence of nonobviousness.

SUMMARY

We affirm the rejection of claims 1, 4, 8-11, 31, 35, 36, 42, 43, 49, 55, 59 and 64 on the ground of nonstatutory obviousness-type double patenting over claims 1-23 of US 7,230,024.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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lp

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